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(71) Applicant *(for all designated States except US)*: THE UNIVERSITY OF IOWA RESEARCH FOUNDATION [US/US]; 100 Oakdale Campus #214 TIC, Iowa City, IA 55242 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: BASKIN, Kevin, M. [US/US]; 1925 Friendship Street, Iowa City, IA 52240 (US). BARNHART, William, H. [US/US]; 1516 California Avenue, Iowa City, IA 52240 (US).

(74) Agents: WAGNER, Vincent, O. et al.; Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).

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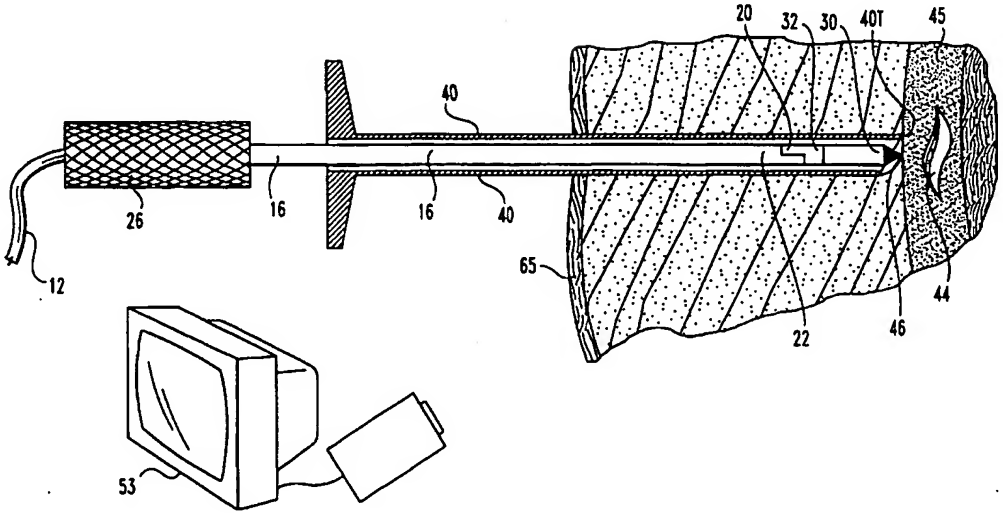

(57) Abstract

A needle localizing assembly is disclosed for marking the location of a bone lesion for subsequent surgical removal. The disclosed localizing assembly includes a localizing needle (14) with a radiation source contained therein to assist the surgeon in manipulating the needle tip, under nuclear medicine visualization, to a marker site near the lesion. The localizing needle (14) is then anchored into the bone. In one embodiment, the assembly includes a starter bit (48) which is introduced through a guiding needle (40) to form a starter hole (56) in the bone into which the screw-tipped localizing needle (14) is screwed to anchor the device to the bone. A driver (16) with an interfitting coupling for transmitting torque to localizing needle (14) is used to screw localizing needle (14) into the bone. In a second embodiment, the localizing needle includes a pair of hooked tips (78, 79) which screw into the bone to anchor the localizing needle to the bone.

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LESION LOCALIZER FOR NUCLEAR MEDICINE

TECHNICAL FIELD OF THE INVENTION

The present invention relates to medical devices for marking locations for subsequent surgery. Particularly, the invention relates to a localizing device utilizing nuclear medicine imaging.

BACKGROUND OF THE INVENTION

It is well known that cancer is a deadly disease. Early detection and treatment are essential to improving a patient's ability to avoid life-threatening complications and to maximize their chances of survival. One such method of early detection involves non-invasive examination of the patient to identify lesions. As these lesion areas may include cancerous or other diseased tissue, once detected they can be surgically removed.

When radiograms or X-rays are used to locate lesions, as in periodic mammogram screens for breast cancer, a guidewire, needle, or similar device can be placed in the tissue as close as possible to the lesion so that the lesion location may be identified during subsequent surgery. As the localizing device and the lesion itself are both visible to radiograms and X-rays, the relative location of the lesion with respect to the localizing device can be determined by examining a radiograph of the lesion site with the localizing device inserted. However, since it is normally impossible to distinguish lesion tissue from normal healthy tissue by sight or feel, and the radiograph is not always available or usable during surgery, the surgeon must rely only on the localizing device and the earlier radiogram to determine the lesion site during surgery. Accurate determination of the location of the lesion from the localizing device allows the surgeon to approach the site accurately, remove a relatively small amount of tissue and yet still be confident that all the lesion tissue is removed. Several devices have been directed toward increasing the accuracy of localizer

placement with respect to the lesion site. For example, inventions to more securely anchor the localizing device in the tissue to prevent inadvertent localizer movement prior to surgery are disclosed in U.S. Pat. Nos. 4,616,656 to Nicholson et al. and 5,221,269 to Miller et al. Additionally, a device which incorporates radiopaque markings at predetermined positions along the axial length of the localizer to further assist in identifying the relative location of the lesion is disclosed in U.S. Patent No. 5,409,004 to Sloan.

However, many lesions are undetectable through radiographic means due to their depth in the tissue or their proximity to bone material. In these cases, alternative detection means are necessary. One such recently developed alternative involves inoculating the patient with a radioactive isotope which preferentially absorbs in lesion tissue. The presence of the radioactive isotope in the lesions makes the lesion visible to nuclear medicine scans.

One limitation generally associated with the prior art localizing devices is that they are insufficiently visible for use with the localizing techniques developed for nuclear medicine scanning. Another limitation of the prior art localizing devices is that they are limited for use in soft tissue material, such as female breast tissue.

SUMMARY OF THE INVENTION

One aspect of the present invention contemplates an apparatus including a radioactive capsule capable of being anchored in bone as a marker for subsequent surgery. Another aspect of the present invention contemplates a method of localizing lesions in hard tissue by installing a radioactive marker securely in bone adjacent the lesion and which has a cable extending from the marker to the exterior of the patient's skin to identify an entry site for subsequent surgery to remove the lesion. The method includes placement of a localizing marker needle with a radiation source imbedded near its distal point, and a flexible cable extending from its proximal end, inside a guide needle. The guide needle with the localizing needle so-installed, is introduced through the patient's skin and observed on a radiation persistence scope, displaying the lesion, which is visible on the scope due to an accumulation of a radioactive isotope in the lesion. The guide needle with the localizing needle therein is advanced with the help of the imaging scope to a point of contact of a needle with the bone adjacent the lesion. According to a method with one embodiment of the invention, the localizing needle has helical hooks at its distal end and, with the guide needle held against the bone, and a torque applying handle connected to the proximal end of the cable, the cable is turned to screw the hooks into the bone. Then the torque-applying handle is removed from the cable, the guide needle is removed, and the portion of the cable outside the body is taped to the skin to be readily located when the patient is moved to a site for subsequent surgery. According to the preferred embodiment of the invention, the localizing needle has a screw threaded point. After locating the threaded point on the bone adjacent the lesion, and then holding the point of the guide needle securely on the bone adjacent the lesion, the localizing needle is withdrawn from the guide needle. Then a sharp-pointed T-handled drill shaft is inserted through the guide needle to the bone and turned to drill a starter hole in the bone. Then the drill is

removed, and the localizing needle re-inserted and the sharp, screw-threaded tip thereof is inserted into the starter hole. A needle driver releasably coupled to the proximal end of the localizing needle and having a handle portion extending outside of the guide needle, is engaged with and used to rotate and thereby drive the screw tip of the localizing needle into the bone for anchorage thereof. When the stability and accuracy of location of the localizing needle relative to the lesion are observed in the scope, the needle driver is removed and the guide needle is removed and the portion of the cable protruding from the skin is then taped to the skin for marking the entrance location for subsequent surgery.

The primary object of the present invention is to provide apparatus and method for providing accurate localization prior to treatment, of sites for surgery or other treatment for bony lesions detectable by radionuclide imaging prior to surgery or other treatment.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side view of a lesion localizing device according to the preferred embodiment of the invention.

Fig. 2 is an enlarged view of the portion of the device opened for filling with radioactive liquid.

Fig. 3 is a sectional view showing the lesion localizing device inside a guide needle and together inserted into body soft tissue toward a lesion site in bone, illustrating a method of marking a lesion and showing the visualization system schematically on a much reduced scale.

Fig. 4 is a sectional view showing the T-handle drill bit extended through the guide needle to the lesion site.

Fig. 5 is a view of the apparatus as in Fig. 3 but where the localizing needle point is screwed into and thereby anchored in the bone at the lesion site

Fig. 6 is a view of the portion of the apparatus remaining after removing the screw driver and guide needle, leaving the localizing needle and cable device marking the lesion site.

Fig. 7 is a side elevational view of a lesion localizing device according to a second embodiment of the present invention.

Fig. 8 is a distal end view of the localizing needle of Fig. 7.

Fig. 9 is an enlarged fragmentary pictorial view of the distal portion of the second embodiment, ready to be closed after installing the radioactive material.

Fig. 10 is a sectional view of the localizing device installed in a guide needle and being anchored in the bone at the lesion site in the patient's body.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

The present invention relates generally to an improved method of localizing lesions in hard tissue by inserting a radioactive capsule into the patient and anchoring it in the bone or other hard tissue near the lesion.

Referring now to Figure 1, a lesion localizer is shown comprising two rigid elongated components and cable **12**. The elongated components comprise distal portions or localizing needle **14** and proximal portion **16** which serves as both a cable sheath and a needle screw driver. Distal portion **14** includes a chamber portion **30** with screw tip **18**, and junction portion **32** with interior end **20**. Proximal portion includes interior end **22** and proximal end **24**. Interior ends **20** and **22** are configured such that when mated, they interfit into a continuous cylinder. Grip end **24** includes hand grip **26** affixed to the outside of the driver **16**. In one preferred embodiment grip **26** is made of a rigid material such as stainless steel integral with needle **16**, and is knurled.

Localizing needle **14** and driver **16** preferably have an outer diameter between 0.6 and 4.0 mm. Cable **12** preferably has a thickness between 0.2 and 0.8 mm. The driver **16** has a central bore of sufficient size for it to freely rotate and slide along cable **12**. Members **14**, **16** and cable **12** are constructed of a biocompatible material or, alternatively, are sheathed in a biocompatible material. Lesion localizer **5** is sized such that it can pass longitudinally through the lumen of a guide needle, such as a

surgical 14 gauge needle, and is of sufficient length (including cable **12**) to reach from the exterior of a patient to the interior lesion site. At a final step in the procedure, upon reaching the lesion site, the localizing needle **14** is anchored near the lesion and driver **16** is then separated from the localizing needle and removed from the cable and guide needle **40**.

The localizing needle **14** is illustrated in detail in **Fig. 2**. It comprises two parts, chamber portion **30** and junction portion **32** which are threaded together at joint **28**. Chamber portion **30** terminates at its distal end in anchoring screw tip **18**. The opposite end is threaded at **34** and is open so that a liquid radioactive agent (technetium, for example) can be placed in chamber **36** therein. Then the chamber is closed and sealed by screwing threads **34** into **38** of junction portion. Screw tip **18** is constructed such that it will screw into bone under application of a torque, to anchor the localizing needle and thereby mark the lesion.

Junction portion **32** comprises interior end **22** and receiver end **38**. Interior end **22** is permanently attached to cable **12**. Receiver end **38** is threaded to receive the threaded end **34** of chamber portion **32**. The threads **34** and **38** are pitched in the same direction as screw tip **18**, so that when the localizing needle **14** is rotated and its screw tip engaged with bone during anchoring, chamber portion **30** does not disengage from junction portion **32**.

The purpose of the proposed device is to assure accurate localization of bony lesions detectable by radionuclide imaging for subsequent excising surgery. First, the lesion **44** of interest is identified under a persistence scope of nuclear medicine visualization camera/monitor systems, using a bone-avid agent. The overlying skin is prepared and draped in a sterile fashion, and local anesthetic infiltrated along the anticipated track of entry.

The use of the lesion localizer **5** is depicted in **Figs. 3, 5 and 6. Fig. 3** shows the localizing needle **14** of localizer **5** introduced into the lumen **42** of the 14 gauge guiding needle **40**. Suitable radioactive material (such as

technetium) already installed in chamber **36**, makes chamber portion **30** of lesion localizer **5** visible to the visualization system. While observing the screen of the scope **53** on which the lesion **44** is visible due to preferential absorption of an ingested radioactive marker in the lesion, a radiologist can guide lesion localizer **5** toward the lesion. Therefore, while observing the screen, the guide needle **40**, with the localizing needle tip **18** at, or immediately behind the guide needle tip, is inserted through the skin and guided toward contact with the bone **45** and marker site **46** proximate the lesion **44**. Then the sharp end of the screw tip **18** is advanced slightly out of needle tip **40T** to slightly penetrate the bone as close as possible to lesion **44**. Then the needle tip **40T** is pushed securely against the bone and held firmly enough to remain in place during the rest of the imaging and the marking procedure. Then, while still viewing lesion **44** and localizer chamber portion **30** under nuclear medicine visualization, the localizer is withdrawn from the proximal end of needle **40**, while being careful not to disturb the position of needle **40**, so that the needle tip **40T** remains engaged with the bone at the marker site **46**. Starter bit **48** is then inserted into needle **40** as shown in **Fig. 4**.

In the preferred embodiment, starter bit **48** includes a T-handle, fixed to the proximal end of shaft **52**, with drill flutes down the shaft to the sharp drill tip **54**. Starter bit **48** is made of sufficiently rigid material, such as stainless steel, such that it can drill a starter hole in bone when torque is applied to T-handle **50**. Of course, the shaft of **52** of starter bit **48** is long enough that it can simultaneously protrude from both ends of needle **40**.

Fig. 4 depicts the T-handle starter shaft **52** inside needle **40** extending to the marker site **46**. The T-handle is used to apply axial force to starter bit **48** along its longitudinal axis, and rotational torque clockwise about its axis to drill a starter hole **56** in the bone cortex at marker site **46**. After starter hole **56** is produced, starter bit **48** is withdrawn from needle **40** while again being careful not to disturb the position of the guide needle **40** with respect to marker site **46**. Then the lesion localizer components are

re-introduced, distal portion with the tip **18** first, and then advanced through needle **40** to starter hole **56**, as shown in **Fig. 6**.

Verification that the needle tip **40T** remains properly in place, and the screw tip **18** has entered the starter hole is done by checking the scanner screen and noting the proximity of chamber portion **30** to the lesion **44.**

Fig. 5 illustrates the anchoring of lesion localizer **5** to marker site **46**. Anchoring is accomplished with the interior ends **20** and **22** interfitting as shown in **Fig. 5**. Then torque is applied to grip **26** of the driver **16** and transferred through the interfitting ends **20, 22** coupling to the screw tip **18** which is thereby screwed clockwise into the bone cortex at the starter hole **56 (Fig. 4)** to a depth of several millimeters, until the screw tip, with the chamber **30**, junction **32** and attached cable end, are firmly fixed in position. As the grip surface **26** for the radiologist, is larger than the driver tube **16**, and is preferably knurled, this makes it easier for the radiologist to screw tip **18** into the bone. When the radiologist is satisfied with the stability of localizer needle **14**, the needle **14** is imaged in two planes. The definitive relationship of the lesion **44** to the small volume of radionuclide in the reservoir chamber **36** should be confirmed prior to withdrawal of the guide needle **40**. The longitudinally extending, adjacent flat surfaces of the interior ends **20** and **22**, of **32** and **16** enable the driver to turn portion **32** either clockwise to drive screw tip **18** in, or counter-clockwise to remove it, if relocation is needed. Portions **30** and **32** must have been screwed tightly together initially to prevent separating during an effort to unscrew tip **18** from bone. If correct initial location is confirmed, the driver **16** and guiding needle **40** can be withdrawn, leaving the localizing needle **14** (with portions **18, 30** and **32** remaining secured together) fixed to the bony cortex, and the attached cable **12** protruding from the needle wound at the skin. The flexible cable portion protruding outside the skin can be fixed to the skin with a plastic film bandage **67** during transport of the patient elsewhere for procedures outside the imaging department, such as excising surgery at

the area marked by the cable. After resection, the bone sample area with the localizing needle **18**, **30**, **32**, in place, should be re-imaged to confirm that the entire radionuclide lesion **44** is contained within the excised sample.

In the later surgery, the surgeon can follow cable **12** to lesion **44**. As suggested above, the radioactive marker anchored in the body near the lesion, allows the lesion location to be triangulated by pre-surgery nuclear medicine visualization, when desired.

Referring now to **Figs. 7-10** showing the other embodiment of the present invention, the localizer includes a cable which is in the form of a tightly-wound wire coil **70** having a junction member **71** affixed to the distal end thereof, the junction member having a thread **72** at the distal end of it. This thread **72** is received in the threaded open end **74** of chamber **76** of the localizing needle **77**. Pointed hooks **78** and **79** are at the distal end of needle **77**. An irradiated material **81** (technetium for example) is placed in the chamber **76**, following which, the needle end is screwed onto the needle junction **72**, closing and sealing the joint at threads **72**. A torque device or handle **82** is screwed onto or otherwise non-rotatably attached to the proximal end portion **83** of cable **70**. In the use of the device as shown in **Fig. 10**, and with the bone lesion **44** being visualized on the screen of the persistence scope, and with the tip **72**, **71** and cable **70** inside the guide needle **40**, the assembly is inserted through the patient's skin **65** and, as the tip assembly **77** is being observed in the scope, it is advanced toward the lesion **44** in the bone, also being observed on the scope. In this example, the tip **40T** of the guide needle is pressed securely against the bone and dug into the bone, if possible, at the marker site **46** and held securely. Then the handle **42** is turned at least one-quarter turn about its axis so that the hooked tips **78** and **79** can dig into the bone to anchor the tip into the bone. When securely anchored, the handle **82** can be unscrewed or unpinned from the cable **70** and removed therefrom, following which the guide needle **40** can be removed from the body along

the cable **70**. Then the portion of the cable protruding from the body at the skin can be taped to the skin as discussed above to remain there until needed later by a surgeon to mark the entry site for surgery.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come with the spirit of the invention are desired to be protected.

What is claimed is:

1. An apparatus to mark the site for treatment of a lesion within tissue, comprising:

a localizing needle assembly having a proximal portion and having a distal portion having a distal end;

at least one of the portions being adapted to exhibit radioactivity; and

means for anchoring said distal portion in said tissue.

2. The apparatus of claim 1 wherein one of said portions has a cavity therein to contain radioactive material; and

said distal portion and said proximal portion are screwed together to close the cavity.

3. The apparatus of claim 1 wherein said anchoring means comprises a screw tip at the distal end of said distal portion.

4. The apparatus of claim 1 wherein said anchoring means comprises hooks at the distal end of said distal portion.

5. The apparatus of claim 1 and further comprising:

a cable having a proximal end and a distal end;

the distal end of the cable being fixed to said proximal portion of said needle assembly.

6. The apparatus of claim 1 and further comprising a torque applicator device mounted to said cable to turn the needle assembly about its longitudinal axis.

7. The apparatus of claim 6 wherein said torque applicator device is removably, but non-rotatably, mounted to the cable.

8. The apparatus of claim 6 wherein said torque applicator device is slidably and rotatably mounted on said cable.

9. The apparatus of claim 8 wherein said torque applicator device and said proximal portion of the needle assembly, have interfittable ends configured to enable bi-directional torque transmission from the torque applicator device to the proximal portion of the needle assembly.

10. The apparatus of claim 1 wherein one of said portions has a cavity therein to contain radioactive material; and

said cavity opens at a junction of said portions and said portions are adapted to be separated to open said cavity, and to be securely joined to close said cavity.

11. The apparatus of claim 10 wherein said cavity is in the distal portion adjacent the distal end of said distal portion of the said localizing needle assembly.

12. The apparatus of claim 11 wherein said radioactive material is contained in the cavity.

13. A marker installation assembly comprising:

the apparatus of claim 5; and

a hollow guide needle having a proximal end and a sharp-tipped distal end for puncturing skin; and

said guide needle is shorter between its ends than is the combination of claim 5; and

the locating needle and part of the cable reside inside the guide needle and are longitudinally moveable therein relative to the distal end of the guide needle.

14. The assembly of claim 13 and further comprising:

a torque applicator device mounted to said cable outside the proximal end of said guide needle.

15. A method for marking the location of a lesion in tissue to be removed during subsequent surgery, said method comprising the steps of:

visualizing the lesion on a nuclear medicine monitor;

placing a localizing needle containing a radiation source in the lumen of a guide needle, with a localizing needle point adjacent the guide needle point and with a cable connected to the localizing needle extending longitudinally in the guide needle lumen and exiting a proximal end of the guide needle;

advancing the assembly of guide needle and localizing needle through the skin of the subject and observing in real time, the path of travel on the monitor and guiding the needle points toward the lesion;

contacting tissue adjacent the lesion with the point of at least one of the needles;

applying a rotational torque to the other of the needles to anchor the said other needle in the tissue; and

removing the guide needle from the cable such that the proximal end of the cable is outside the body of the subject.

16. The method of claim 15 and further comprising the steps of:

prior to removing the guide needle, urging a sharp end of the guide needle against hard tissue adjacent the lesion;

while keeping the guide needle securely engaged with the hard tissue, applying rotational torque to the cable to screw into the hard tissue, two anchor hooks at the tip of the localizing needle to secure it in the hard tissue.

17. The method of claim 15 and further comprising the steps of:

prior to removing the guide needle, pushing a sharp point of the guide needle into the bone adjacent the lesion;

while holding the point of the guide needle securely against and immovably against the hard tissue adjacent the lesion, withdrawing the localizing needle from the guide needle and inserting in the guide needle the sharp point of a drill stylet and engaging the same with the hard tissue;

while engaging the drill bit of the drill stylet with the hard tissue, applying axial force from the portion of the drill stylet outside the guide needle and torsional force to turn the drill bit into the hard tissue and thereby drill a starter hole in the tissue.

18. The method of claim 17 and further comprising the step of:

after drilling the starter hole, and while maintaining the guide needle securely affixed against the hard tissue adjacent the lesion, withdrawing the drill stylet and re-inserting the localizing needle so that its point enters the starter hole; and

driving the localizing needle into the hole while turning the localizing needle tip in the hole and thereby screwing the localizing needle into the starter hole and thereby securing it in the hard tissue adjacent the lesion.

19. The method according to claim 18 and further comprising the step of:

after screwing the screw tip of the localizing needle into the hard tissue and thereby anchoring it into the hard tissue, removing

from the cable, the guide needle and a localizing needle screw driver.

20. The method of claim 19 and further comprising the step of:

after removing the guide needle, taping to the skin that portion of the cable protruding through the skin toward the proximal end of the cable.

21. The method of claim 18 and further comprising the step of:

after anchoring the localizing needle point in the hard tissue, visualizing the localizing needle point and lesion in two image planes to confirm the proper location of the localizing needle relative to the lesion, before withdrawing the guide needle.

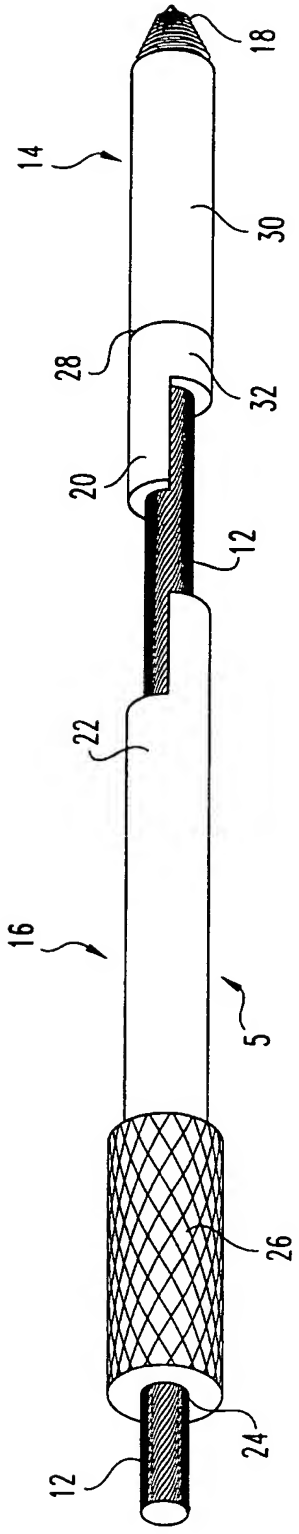

Fig. 1

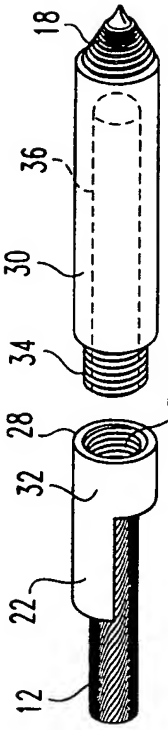

Fig. 2

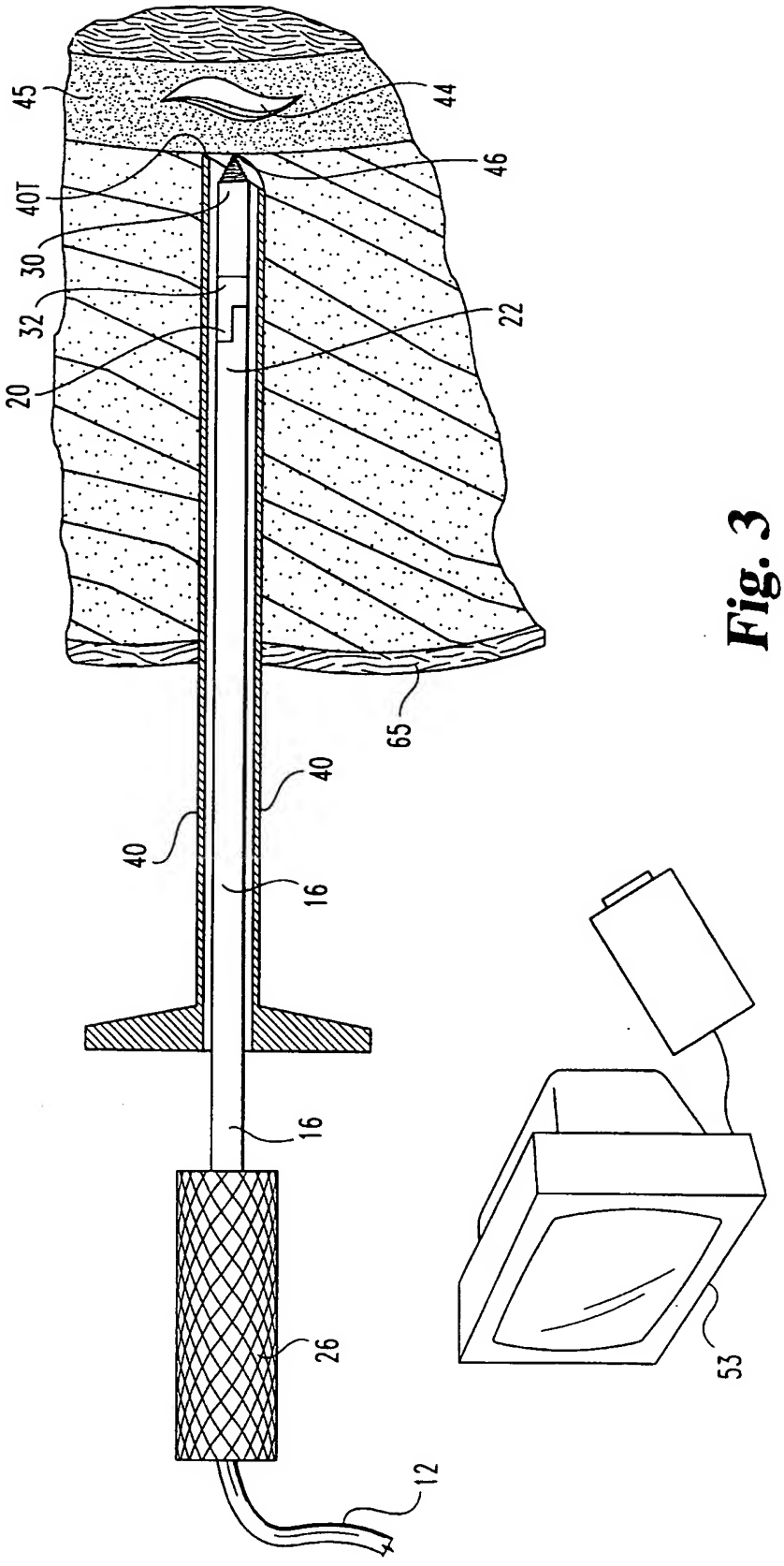

Fig. 3

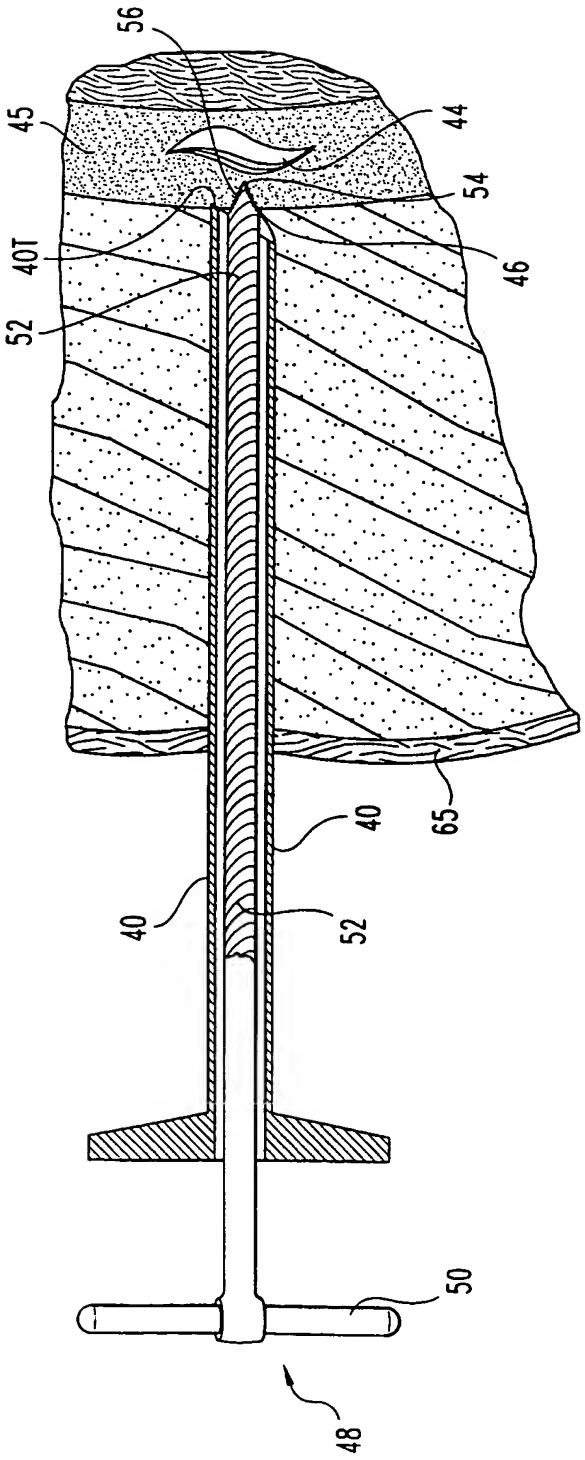

Fig. 4

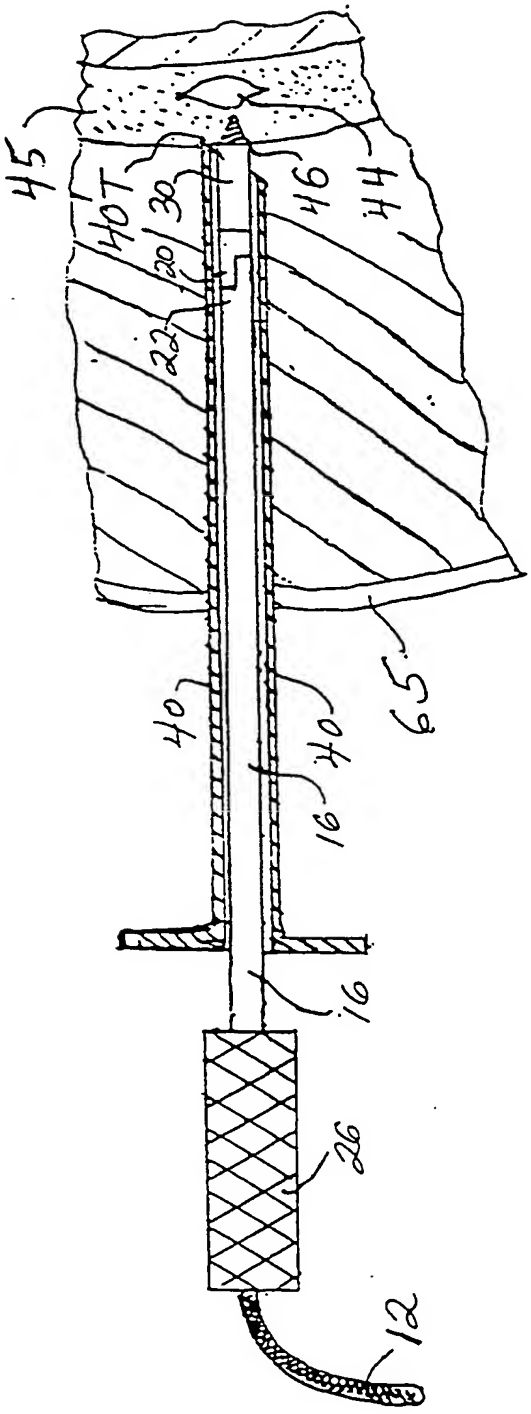

FIG. 5

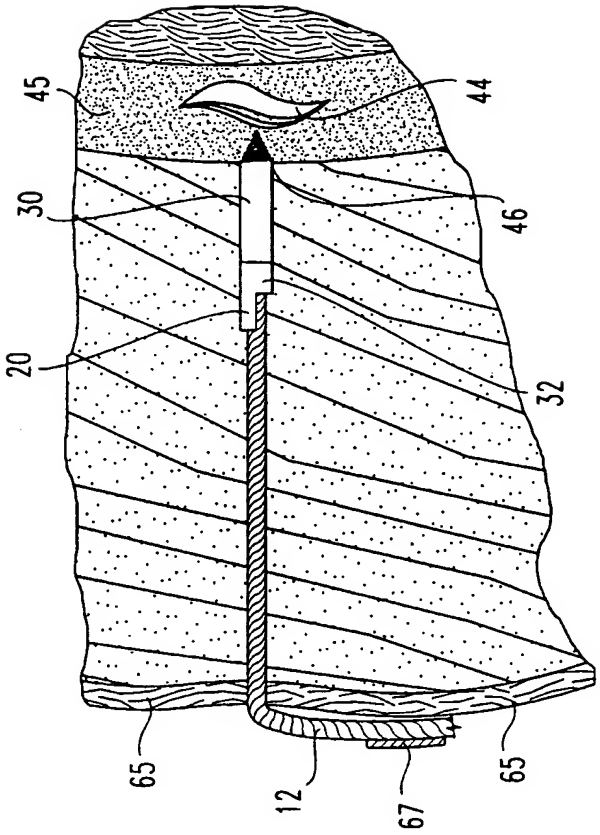

Fig. 6

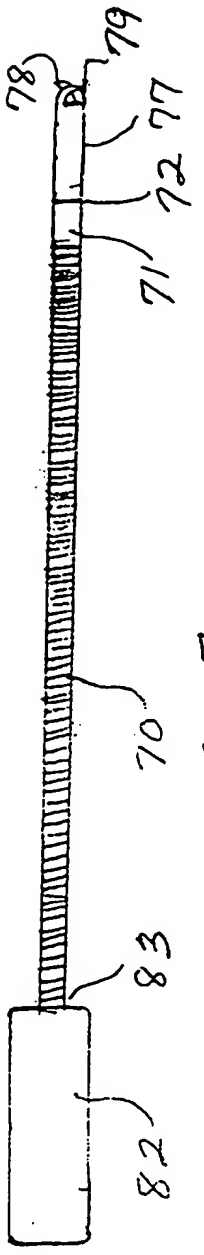

FIG. 7

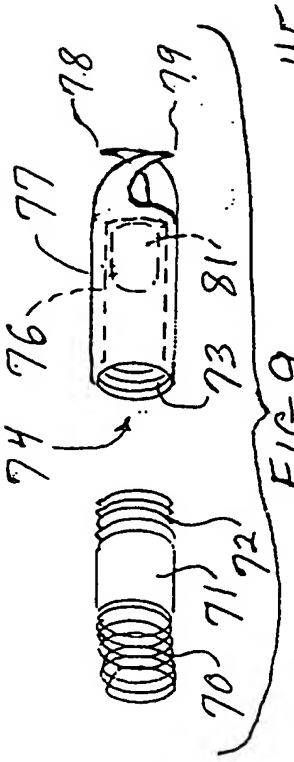

FIG. 9

FIG. 8

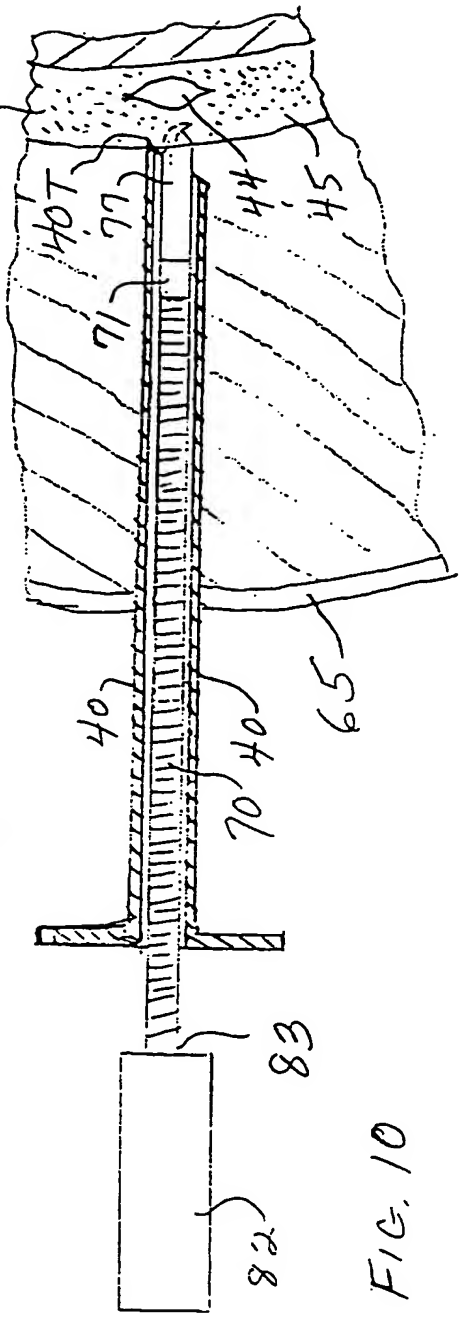

FIG. 10

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/03366

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 647 374 A (CUTRER) 15 July 1997 see column 3, line 45 - line 55; figure 2	1
Y	US 5 665 092 A (MANGIARDI ET AL) 9 September 1997 see column 3, line 41 - line 43 see column 4, line 45 - column 5, line 13 see column 5, line 38 - line 44 see column 6, line 1 - line 8 see column 6, line 59 - line 65; figures 1,3,15-20	1,3-9, 13,14
Y	US 4 781 198 A (KANABROCKI EUGENE L) 1 November 1988 see column 2, line 3 - line 8; figure 2	1,3-9, 13,14
A	FR 2 686 499 A (TECHNOMED) 30 July 1993 see claim 9; figure 2	1

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 June 1999	06/07/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Moers, R

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INTERNATIONAL SEARCH REPORT

Inter...ional Application No
PCT/US 99/03366

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 687 739 A (MCPHERSON ET AL.) 18 November 1997 see column 6, line 66 - column 7, line 17; figure 7	1
A	DE 39 37 052 A (INSTRUMENTARIUM CORP.) 17 May 1990 see column 5, line 34 - line 47 see column 6, line 46 - line 52; figure 5	1
A	WO 94 17733 A (FITZPATRICK J MICHAEL ;MACIUNAS ROBERT J (US); WILLCOTT M ROBERT ( ) 18 August 1994 see abstract; claim 35; figure 1	2,10-12
A	US 2 269 458 A (KAHN) 13 January 1942 see page 1, column 2, line 4 - line 15; figure 1	2,10-12

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/03366

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15-21
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. ..ional Application No
PCT/US 99/03366

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5647374 A	15-07-1997	NONE	
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		US 5595193 A	21-01-1997
		US 5799099 A	25-08-1998
		US 5769789 A	23-06-1998
US 2269458 A	13-01-1942	NONE	